

## **REMARKS**

Claims 63-65, 67-69 have been canceled, and claims 66, 70-73 and 76 have been amended. Thus, claims 66, 70-76 are pending in this application.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

### **I. OBJECTIONS TO THE SPECIFICATION**

The examiner objects to the specification on several grounds.

In paragraph 7 of the Office Action, the examiner again requests that sequence identifiers be added wherever an amino acid is mentioned. Applicants maintain repetitive citations to the referenced sequence are not required in view of the clear explanation provided in the specification. Nevertheless, to advance prosecution applicants have amended the specification and believe thereby to have obviated the objection.

In paragraph 8, the examiner identified additional instances where the specification incorrectly recites Asn542 instead of Asn452. Applicants believe the submitted amendments obviate the objection.

Also in paragraph 8, the examiner asserts that the recitation of Cys478 is confusing, allegedly because the TACE molecule has only 477 residues. As noted previously, the specification's recitation of particular amino acid sequences of TACE refers to the sequence disclosed in Black *et al.*, *i.e.* full-length TACE (SEQ ID NO: 7), not the 1-477 fragment of SEQ ID NO: 8. Applicants, therefore, believe no further clarification is required.

The examiner, in paragraph 9, objects to the use of color figures. Applicants enclose herewith another Petition to Accept Color Drawings.

### **II. REJECTIONS UNDER 35 U.S.C. § 112 ¶2**

The examiner rejects claims 67 and 74-76 under 35 U.S.C. §112, ¶2, for alleged indefiniteness. Applicants traverse the rejection.

As noted previously, the commonly applied test for the requisite precision is whether one skilled in the art would understand the metes and bounds of the claim when read in light of the specification. *See Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). Claims 67 and 74 are directed to, *inter alia*, computerized systems for

depicting and analyzing TACE polypeptides, in which systems the data structure of the memory of the computerized system is organized in a particular way. For example, the claimed computerized systems comprise at least one first-type storage region, comprising a set of spatial coordinates of a TACE polypeptide in a three-dimensional space and at least one second-type storage region, comprising a representation of characteristics of a plurality of amino acids of the polypeptide. The second-type storage region is logically associated with the first-type storage region to support data processing in the processor. Furthermore, the specification describes the physical nature of the data structure. *See, e.g.*, Substitute specification, pgs. 29-31. *See also* Figure 6.

Accordingly, applicants assert that an artisan would understand the metes and bounds of the claimed invention in light of the specification. Applicants request, therefore, that the rejection be withdrawn.

### **III. REJECTIONS UNDER 35 U.S.C. § 112 ¶1**

The examiner rejects claims 63-65 under 35 U.S.C. §112, ¶1, for allegedly containing “new matter.” Applicants respectfully traverse the rejection.

Though citing 35 U.S.C. §112, ¶1, the examiner has rejected the claims for alleged “new matter.” Indeed, the examiner summarily dismissed applicant’s arguments with respect to written description chiefly because they did not address the issue of “new matter.” Final Office Action, pg. 5, ¶4.

In so doing, the examiner has committed a legal error. As a matter of law, claims cannot be rejected for lacking “new matter.” *See, e.g., In re Rasmussen*, 650 F.2d 1212, 1214 (CCPA 1981); *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003). It is well-established that “[t]he proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure . . . is §112, first paragraph, not § 132.” *In re Rasmussen*, 650 F.2d at 1214. Meanwhile, a “new matter” rejection under 35 U.S.C. §132 is limited to objections to “amendments to the abstract, specifications, or drawings.” *Id.*

In levying a written description rejection under §112, an examiner has the burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant’s disclosure, a description of the invention defined by the claims.

*See In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976). As noted previously, applicants believe the examiner has failed to meet this burden.

Nevertheless, applicants have cancelled claims 63-65, thereby rendering the rejection moot. Applicants, however, reserve the right to pursue similar claims in a subsequent application.

The examiner also rejects claims 66-76 under 35 U.S.C. §112, ¶1, for allegedly containing “new matter.” As noted above, as a matter of law, claims cannot be rejected for containing “new matter.” Thus, the rejection is legally flawed.

In any event, applicants have proposed amendments which would render the objection moot. Accordingly, applicants request that the rejection be withdrawn.

The examiner also rejects claims 63, 65 and 66-76 under 35 U.S.C. §112, ¶1, for allegedly failing to convey to one of skill in the art that applicants possessed the claimed genus. According to the examiner, the specification fails to provide a representative number of species for the claimed genus. Applicants respectfully traverse the rejection.

The examiner asserts that “when varying structures are present in the genus, the *Enzo Biochemical* analysis applies wherein a representative number of species is required . . . **and** a correlation between structure and function must be set forth.” Final Office Action, pg. 7, ¶4 (emphasis added). As a matter of fact, the Federal Circuit in *Enzo Biochem, Inc.* did not hold that the written description requirement for a claimed genus requires a representative number of species **and** a correlation between structure and function. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002). Indeed, the court stated that just a correlation between structure and function will suffice and remanded the case for consideration of this matter. *Id.* at 968. Similarly, the USPTO’s Guidelines for “Written Description” state that possession of a claimed genus can be established merely with a correlation between structure and function. *See* Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶1, “Written Description” Requirement, 66 Fed. Reg. 1099 (2001). Thus, by requiring applicants to demonstrate both a representative number of species and a correlation between structure and function, the examiner has committed a legal error.

The examiner also errs factually by asserting that “no specific structure is required in the claims.” As a matter of fact, the claimed computerized systems require structural data obtained from crystallographical analysis of a TACE polypeptide comprising a catalytic

domain. The TACE catalytic domain defines the functionality of TACE polypeptides. That is, the TACE catalytic domain is the active site of the enzyme and is responsible for cleaving membrane-bound TNF $\alpha$ , thereby “converting” the membrane-bound TNF $\alpha$  into soluble TNF $\alpha$ .

Thus, applicants have demonstrated possession of the claimed genus by disclosing and claiming the relevant structure responsible for the functionality that defines the genus. Accordingly, the examiner has erred by objecting to the number of representative species. Applicants, therefore, request that the rejection be withdrawn.

#### **IV. REJECTIONS UNDER 35 U.S.C. §§ 102 & 103**

The examiner rejects claims 66-69 and 74-76 under 35 U.S.C. §102(a) as allegedly being anticipated by Cirilli. The examiner further rejects claims 70-73 under 35 U.S.C. §103 for allegedly being unpatentable over Cirilli.

The examiner asserts that there is no difference between the computerized system referenced in Cirilli and the claimed invention. In particular, the examiner states that “the data obtained from the x-ray analysis of Cirilli *et al.* is no different from the data obtained by other means.” Final Office Action, pg. 8, ¶5. Applicants respectfully disagree.

The only X-ray analysis disclosed by Cirilli concerned adamalysin II, not TACE. Furthermore, Cirilli did not disclose, nor did the referenced computer system contain, the atomic coordinates for TACE. Cirilli merely performed a “structure-based sequence alignment of adamalysin II and TACE . . . using the program MODELLER.” Cirilli *et al.*, at pg. 321, right column, ¶4.

Indeed, applicants were the first to elucidate the atomic coordinates of the TACE catalytic domain. With this insight, applicants developed computer systems containing the elucidated coordinates for depicting and analyzing a TACE polypeptide. As the cited art, neither taught nor suggested such computer systems, the rejections under §102(a) and §103 should be withdrawn.

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Applicant believes that the present application is now in condition for allowance.  
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a  
telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date 2 March 2005

By 

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